

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:.	Brugger, et al.	}	
		}	
Serial No.:	To be assigned	}	
		}	
Filed:	Herewith	}	Group Art No: To be assigned
		}	Examiner: To be assigned
		}	
For:	Differential Fluid Parameter Determination	}	
		}	
Customer No.:	24994	}	

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. § 1.56, Applicant brings to the attention of the Examiner the documents listed on the attached form PTO 1449. It is believed this Information Disclosure Statement is being filed before the first Office Action on the merits.

As shown in the Preliminary Amendment being filed herewith, this application is a continuation of US Patent Application Serial No. 10/238,164 filed September 10, 2002, which is a continuation of US Patent Application Serial No. 09/563,107 filed May 2, 2000, which is a continuation of U.S. Patent Application Serial No. 09/220,139 filed December 23, 1998, now 6,075,367; which is a continuation of U.S. Patent Application Serial No. 08/876,445 filed June 16, 1997, now US. Patent No.5,900,726; which was a continuation of U.S. Patent Application Serial No. 08/486,982 filed June 7, 1995, now U.S. Patent No. 5,644,240; which was a continuation-in-part of U.S. Patent Application Serial No. 08/332,647 filed November 1, 1994, now U.S. Patent No. 5,510,716; which was a continuation of U.S. Patent Application Serial No. 07/954,584 filed September 30, 1992,

now abandoned. Per 37 C.F. R. §1.98(d), the Examiner is respectfully referred to the files of those applications for copies of the documents listed on the attached form PTO 1449.

This submission does not represent that a search has been made or that no better information exists and does not constitute an admission that each or all of the listed documents alone or in combination, are considered to be material to patentability as defined under 37 C.F.R. § 1.56(b).

It is believed no fee is required in connection with the filing of this statement. If this is incorrect, please charge deposit account 03-2316.

Respectfully submitted,

1/29/03
Date

Edna M O'Connor
Edna M. O'Connor
Registration No: 29 252
Gambro, Inc.
10810 W. Collins Ave.
Lakewood, Colorado 80215
Tel. (303) 231-4132

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>				ATTY DOCKET NO. RC-0011-P22		SERIAL NO To be assigned		
				FILING Herewith		GROUP To be assigned		
U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
		2,709,785	5/31/55	Fielden				
		3,396,331	8/6/68	Sperry III				
		3,404,336	10/1/68	Rosenthal				
		3,482,575	12/9/69	Claff, et al.				
		3,491,592	1/27/70	Evers, et al.				
		3,619,423	11/9/71	Galletti, et al.				
		3,722,276	3/27/73	Chandler, et al.				
		3,867,688	2/18/75	Koski				
		3,980,946	9/14/76	Fleury				
		4,081,372	3/28/78	Atkin, et al.				
		4,136,563	1/30/79	Mueller et al.				
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		190873/85	1985	Japan				
		36990/77	1977	Japan				
		2026508	5/1/92	Spain				
		EP 0 272 414	6/29/88	Europe			✓	
		EP 0 097 366	1/4/84	Europe				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
		Robert L. Hester, Ph.D., "A New Technique for Determining Recirculation in the ESRD Patient", Nephrology News & Issues, pp. 44-55, June 1993, Jackson, MS						
		Gambro, "FAM 10 Fistula Flow Studies and Their Interpretation", pp. 1-31, Lund Sweden, published on or before September 29, 1991.						
		Salamon et al. "Translation: low frequency electrodeless conductometer for measuring the electrical conductivity of solutions, 1959, Industrial Group Headquarters, Risley, Warrington, Lancashire, GB						
EXAMINER				DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>	ATTY DOCKET NO. RC-0011-P12	SERIAL NO. To be assigned
	FILING Herewith	GROUP To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,138,639	2/6/79	Hutchins			
	4,181,610	1/1/80	Shintani, et al.			
	4,361,049	11/30/82	Volgyesi			
	4,508,622	4/2/85	Polaschegg, et al.			
	4,650,458	3/17/87	Dahlberg, et al.			
	4,739,492	4/19/88	Cochran			
	4,740,755	4/26/88	Ogawa			
	4,825,168	4/25/89	Ogawa, et al.			
	4,995,268	2/26/91	Ash, et al.			
	5,004,459	4/2/91	Peabody, et al.			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	2093192	8/25/82	United Kingdom				
	521891	10/6/76	U.S.S.R. (cover page)				✓
	1013853	4/23/83	U.S.S.R.				✓

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		Richard A. Sherman, "Recirculation Revisited", Seminars in Dialysis, Vol. 4, No. 4, pp. 221-223,
		Oct-Dec 1991, New Jersey

EXAMINER	DATE CONSIDERED
----------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>				Docket Number (Optional) RC-0011-P22		Application Number To be assigned		
				Applicant(s)				
				Filing Date Herewith		Group Art Unit To be assigned		
U.S. PATENT DOCUMENTS								
EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APFR PRIATE	
		5,092,836	3/3/92	Polaschegg				
		5,453,576	9/26/95	Krivitski				
		5,510,716	4/23/96	Buffaloe, IV, et al.				
		5,510,717	4/23/96	Buffaloe, IV, et al.				
		5,595,182	6/21/97	Krivitski				
		5,685,989	11/11/97	Krivitski, et al.				
		3,450,984	6/17/69	Holmes				
		5,312,550	5/17/94	Hester				
		3,324,720	6/13/67	Sutherland				
FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>								
		McKamy SMith, "Cardiac Output Determined by the Saline Conductivity Method Using an Extraarterial Conductivity Cell", Cardiovascular Research Center Bulletin, Vol. 5, No. 4, pp. 123-134, April-June 1967, Texas						
EXAMINER				DATE CONSIDERED				
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>	ATTY DOCKET NO. RC-0011-P22	SERIAL NO. To be assigned
	FILING Herewith	GROUP To be assigned

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPR PRIATE	

FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>			
EXAMINER	INITIAL	DATE	J.S. Gani et al., "Use of the Fistula Assessment Monitor to Detect Stenoses in Access Fistulae," (abstract) Australian Society of nephrology, 1989, Australia
			Jonathan S. Gani, "Use of the Fistula Assessment Monitor to Detect Stenoses in Access Fistulae," American Journal of Kidney Diseases, Vol. XVII, No. 3, pp. 303-306, March 1991, Newcastle, Australia
			R N Greenwood et al. "Assessment of Arteriovenous Fistulae from Pressure and Recirculation Studies. Clinical Experience in 186 Fistulae", Abstract, pg. 106, 1985, London, U.K.
			R N Greenwood et al., "Assessment of Arteriovenous Fistulas From Pressure and Recirculation Studies: Clinical Experience in 215 Upper Limb Fistulas, EDTA-ERA," Vol. 22, pp. 296-302, 1985, London, U.K.

EXAMINER	DATE CONSIDERED
----------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>	ATTY DOCKET NO. RC-0011-P22	SERIAL NO. To be assigned
	FILING Herewith	GROUP To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		R N Greenwood et al., "Assessment of Arteriovenous Fistulae from Pressure and Thermal Dilution Studies: Clinical Experience in Forearm Fistulae," Clinical Nephrology, Vol. 23, No. 4, pp. 189-197, 1985, U.K.
		L. Goldstein et al., "The Assessment of Arteriovenous Fistulae From Pressure and Recirculation Studies:, Porc EDTNA-ERCA, Vol. 14, pp. 207-215, 1985, United Kingdom
		Lynn W. Hart et al., "A Noninvasive Electromagnetic Conductivity Sensor for Biomedical Applications:, IEEE Transactions on Biomedical Engineering, Vol. 35, No. 12, pp. 1011-1022, December 1988, Maryland
		Robert L. Hester et al., "The Determination of Hemodialysis Blood Recirculation Using Blood urea nitrogen Measurements", American Journal of Kidney Diseases, Vol. XX, no. 6, pp. 598-602, December 1992, Mississippi

EXAMINER	DATE CONSIDERED
-----------------	------------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>	ATTY DOCKET NO. RC-0011-P22	SERIAL NO. To be assigned
	FILING Herewith	GROUP To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		Transonic Systems, Inc., "Transonic Hemodialysis Monitor Measures Access Flow Recirculation Cardiac Output Routinely during Dialysis", April 1995
		Nikolai M. Krivitski, "Novel Method to Measure Access Flow During Hemodialysis by Ultrasound Velocity Dilution Technique", July 27, 1995, ASAIO Journal, pages 0014-0018
		Thomas A. Depner and Nikolai M. Krivitski, "Clinical Measurement of Blood Flow in Hemodialysis Access Fistulae and Grafts by Ultrasound Dilution", July 27, 1995, ASAIO Journal, pages 0018-0022
		Thomas A. Depner et al., "Hemodialysis Access Recirculation Measured by Ultrasound Dilution", July 27, 1995, ASAIO Journal, pages 0022-0026

EXAMINER	DATE CONSIDERED
----------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION <i>(Us several sheets if necessary)</i>	ATTY DOCKET NO. RC-0011-P22	SERIAL NO. To be assigned
FILING Herewith	GROUP To be assigned	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		N.M. Krivitski, "Novel Method to Measure Access Flow During Hemodialysis by Ultrasound Dilution (UD)", ASAIO Journal 1995
		Nikolai M. Krivitski, "Theory and Validation of Access Flow Measurement by Dilution Technique during Hemodialysis", Kidney International, Vol. 48 (1995), pages 244-250
		N.M. Krivitski, "Accuracy of Ultrasound Dilution Method to Measure Access Flow (AF) in Hemodialysis", XIIIth International Congress of Nephrology, Abstract, 1995

EXAMINER	DATE CONSIDERED
-----------------	------------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>	ATTY DOCKET NO. RC-0011-P22		SERIAL NO. To be assigned
	FILING Herewith		GROUP To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		Nikolai Krivitski, Ph.D. "New Method to Measure Recirculation (Rc) and Access Flow During Hemodialysis (HD)" American Nephrology Nurses' Association 26th National Symposium Exhibitor Continuing Education Program, Abstract, 1995
		T. Depner, "Changes in Access Blood Flow (Qac) and Appearance of Recirculation (RC) During Hemodialysis", XIIIth International Congress of Nephrology, Abstract, 1995
		T.A. Depner et al., "Hemodialysis Access Recirculation (Rc) Measured by Ultrasound Dilution", ASAIO Journal 1995 Abstracts, Supplement to January-March 1995 Volume 41, No. 1, page 80

EXAMINER	DATE CONSIDERED
----------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>	ATTY DOCKET NO. RC-0011-P12	SERIAL NO. To be assigned
	FILING Herewith	GROUP To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

		T.A. Depner and N.M. Krivitski, "Clinical Measurement of Blood Flow in Hemodialysis Access Fistulae and Grafts by Ultrasound Dilution", ASAIO Journal 1995 Abstracts, Supplement to January-March 1995 Volume
		41, No. 1, page 80
		Transonic Systems Inc., "Recirculation, Access Flow Measurements", 1995, pages 19-26
		N.M. Krivitski, "Cardia Output Measurement in Extracorporeal Systems by Ultrasound Velocity Dilution", ASAIO Abstracts, 1994, page 82

EXAMINER	DATE CONSIDERED
----------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)

RC-0011-P22

Application Number

To be assigned

Applicant(s)

Filing Date

Herewith

Group Art Unit

To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	3						

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		John L. Noshier, Death Taxes, and Vascular Access Dysfunction, Seminars in Dialysis, Vol. 4, No. 2, pp. 67-68, Apr-June 1991, New Jersey
		In-Lin Diagnostics (brochure) "Improve the Clinical Outcome of Every Patient!", four pages, (undated)
		In-Line Diagnostics (brochure) "Non-Invasive Blood Volume Monitoring", two pages, 1994
		In-Line Diagnostics (brochure) "The Crit-Line System", two pages, (undated)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Docket Number (Optional)
RC-0011-P12

Application Number
To be assigned

Applicant(s)

Filing Date
Herewith

Group Art Unit
To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	3						

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		John D. Bower and Thomas G. Coleman, "Circulatory Function During Chronic Hemodialysis", Vol. XV Trans. Amer. Soc. Artif. Int. Organs, 1969, pp. 373-377

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Docket Number (Optional)

RC-0011-P22

Application Number

To be assigned

Applicant(s)

BRUGGER, James

Filing Date

Herewith

Group Art Unit

To be assigned

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		J.H. Meijer et al., "Analysis of Recirculation in Single-needle Haemodialysis", Med. & Biol. Eng. & Comput., 1979, 17, 578-582

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.